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| 10/782,627 | 02/18/2004 | John C. Reed | 66821-276 | 5834 |

7590 01/04/2008
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| EXAMINER |
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RAWLINGS, STEPHEN L

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| ART UNIT | PAPER NUMBER |
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1643

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01/04/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|----------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/782,627 | REED ET AL. | |
| | Examiner | Art Unit | |
| | Stephen L. Rawlings, Ph.D. | 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 October 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 2-33 is/are pending in the application.
 - 4a) Of the above claim(s) 6-33 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 2-5 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 18 February 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
- 6) Other: See Continuation Sheet.

Continuation of Attachment(s) 6). Other: Notice of Non-Compliant Amendment.

DETAILED ACTION

1. The amendment filed October 16, 2007, is acknowledged and has been entered. Claim 34 has been canceled. Claims 2-5 have been amended.
2. Claims 2-33 are pending in the application. Claims 6-33 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on October 26, 2006.
3. Claims 2-5 are currently under prosecution.
4. The following Office action contains NEW GROUNDS of rejection necessitated by amendment.

Oath/Declaration

5. Receipt of the new declaration filed October 16, 2007, is acknowledged; however, it is defective. A new oath or declaration in compliance with 37 C.F.R. § 1.67(a) identifying this application by application number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02.

The declaration is defected for the following reason: It does not state that the person making the oath or declaration believes the named inventor **or inventors** to be the original and first inventor **or inventors** of the subject matter which is claimed and for which a patent is sought. See 37 C.F.R. § 1.63.

Response to Amendment

6. The amendment filed on October 16, 2007, is considered non-compliant because it fails to meet the requirements of 37 CFR § 1.121, as amended on June 30, 2003 (see

68 Fed. Reg. 38611, Jun. 30, 2003). However, in order to advance prosecution¹, rather than mailing a Notice of Non-Compliant Amendment, Applicant is advised to correct the following deficiency in replying to this Office action:

The amendment to the specification is non-compliant because the replacement abstract must be presented on a separate sheet, as required under 37 C.F.R. § 1.72.

Only the corrected section of the non-compliant amendment must be resubmitted (in its entirety), e.g., the entire “Amendments to the claims” section of applicant’s amendment must be re-submitted. 37 CFR § 1.121(h).

Grounds of Objection and Rejection Withdrawn

7. Unless specifically reiterated below, Applicant’s amendment and/or arguments filed as part of the response of October 16, 2007, have obviated or rendered moot the grounds of objection and rejection set forth in the previous Office action mailed April 16, 2007.

For clarity the rejection of claims 2-5 under 35 U.S.C. § 102(b) has been withdrawn because Takayama et al. (*Genomics*. 1996; 35: 494-498) teaches a substantially purified nucleic acid molecule comprising, but not consisting of the polynucleotide sequence set forth as SEQ ID NO: 1; see entire document (e.g., 495, Figure 1). As presently amended, claims 2-5 are directed to a nucleic acid molecule consisting of, rather than comprising the nucleotide sequence of SEQ ID NO: 1.

Ground of Objection Maintained

Specification

8. The objection to the specification because the use of improperly demarcated trademarks is maintained. Although the use of trademarks is permissible in patent

¹ See M.P.E.P. § 714.03.

applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Additional example of an improperly demarcated trademark appearing in the specification is BiaCore™; see, e.g., page 33, line 2.

Again, appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine under "USPTO Search Collections" on the Internet at <http://www.uspto.gov/web/menu/search.html>.

9. The objection to the abstract of the disclosure because it is entitled "Abstract of the Invention", where it should be entitled "Abstract" or "Abstract of the Disclosure", is maintained. Correction is required. See MPEP § 608.01(b).

Notably, although Applicant has made a bona fide attempt to correct this issue, the amendment to the specification is non-compliant, as explained above. Accordingly, this ground of objection is maintained.

Ground of Rejection Maintained

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140

F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. The rejection of claims 2-5 on the ground of nonstatutory obviousness-type double patenting, as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,696,558 B2, is maintained.

Although the conflicting claims are not identical, they are not patentably distinct from each other for the following reasons:

Claims 1 and 2 of the patent are drawn to a substantially purified nucleic acid molecule having the nucleotide sequence of SEQ ID NO: 1 and a substantially purified nucleic acid molecule having a nucleotide sequence comprising nucleotides 46-1291 of SEQ ID NO: 1, respectively.

In contrast to claims 1 and 2 of the patent the instant claims are directed to a nucleic acid molecule consisting of the nucleotide sequence of SEQ ID NO: 1; see, e.g., claim 2.

Accordingly, the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter

claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application.

At page 11 of the amendment filed October 16, 2007, Applicant has requested that this issue be held in abeyance.

This rejection will be maintained until it is obviated by amendment to the claims in this application or until it is otherwise remedied by an appropriate course of action (e.g., the filing of an effective terminal disclaimer). See 37 C.F.R. § 1.111(b). See M.P.E.P. § 714.02.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 5 is drawn to the nucleic acid of claim 3, which is complementary to the nucleotide sequence that encodes the protein of SEQ ID NO: 2; but according to claim 3, the nucleic acid consists of a nucleotide sequence that encodes this protein. A nucleic acid consisting of a nucleotide sequence encoding the protein of SEQ ID NO: 2 cannot also consist of a nucleotide sequence that is complementary to the nucleotide sequence encoding the protein.

It is suggested that this issue be remedied by amending claim 5 to recite, for example:

A nucleic acid consisting of a nucleotide sequence that is fully complementary to a nucleotide sequence encoding the functionally active BAG family protein of SEQ ID NO: 2.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

15. Claims 2-5 are rejected under 35 U.S.C. 102(a) as being anticipated by Takayama et al. (*GENEMBL Accession Number AF022224; 03 September 1998*).

The claims are drawn to a substantially purified nucleic acid molecule having the polynucleotide sequence set forth in SEQ ID NO: 1, which encodes the protein of SEQ ID NO: 2.

Takayama et al. teaches a substantially purified nucleic acid molecule consisting of an identical polynucleotide sequence as that set forth in SEQ ID NO: 1; see entire document.

Conclusion

16. No claim is allowed.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephen L. Rawlings/
Stephen L. Rawlings, Ph.D.
Primary Examiner
Art Unit 1643

slr
December 12, 2007

**Notice of Non-Compliant
Amendment (37 CFR 1.121)**

| | | |
|----------------------------|--------------|--|
| Application No. | Applicant(s) | |
| 10/782,627 | REED ET AL. | |
| Examiner | Art Unit | |
| Stephen L. Rawlings, Ph.D. | 1643 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 16 October 2007 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING CHECKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- 1. Amendments to the specification:
 - A. Amended paragraph(s) do not include markings.
 - B. New paragraph(s) should not be underlined.
 - C. Other _____.
- 2. Abstract:
 - A. Not presented on a separate sheet. 37 CFR 1.72.
 - B. Other _____.
- 3. Amendments to the drawings: _____.
- 4. Amendments to the claims:
 - A. A complete listing of all of the claims is not present.
 - B. The listing of claims does not include the text of all pending claims (including withdrawn claims).
 - C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following 7 status identifiers: (Original), (Currently amended), (Canceled), (Withdrawn), (Previously presented), (New) and (Not entered).
 - D. The claims of this amendment paper have not been presented in ascending numerical order.
 - E. Other: _____.

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714 and the USPTO website at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognitice/officeflyer.pdf>.

PRELIMINARY AMENDMENT AND NON-FINAL AMENDMENT:

If the non-compliant amendment is a **PRELIMINARY AMENDMENT**, applicant is given ONE MONTH, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the corrected section which complies with 37 CFR 1.121. Failure to comply with 37 CFR 1.121 will result in non-entry of the preliminary amendment and examination on the merits will commence without consideration of the proposed changes in the preliminary amendment(s). This notice is not an action under 35 U.S.C. 132, and this **ONE MONTH time limit is not extendable**.

If the non-compliant amendment is a reply to a **NON-FINAL OFFICE ACTION** (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), and since the amendment appears to be a *bona fide* attempt to be a complete reply (37 CFR 1.135(c)), applicant is given a TIME PERIOD of ONE MONTH, or thirty (30) days, whichever is longer, from the mailing of this notice within which to re-submit the corrected section which complies with 37 CFR 1.121 in order to avoid abandonment. **EXTENSIONS OF THIS TIME PERIOD ARE AVAILABLE UNDER 37 CFR 1.136(a)**.

Only the corrected section of the non-compliant amendment document must be resubmitted (in its entirety), e.g., the entire "Amendments to the claims" section of applicant's amendment document must be re-submitted. 37 CFR 1.121(h).

AFTER-FINAL AMENDMENT:

If the amendment is a reply to a **FINAL REJECTION**, this form may be an attachment to an Advisory Action Before the Filing of an Appeal Brief (PTOL-303). **The period for reply to a final rejection continues to run from the mailing date of the final Office action**, and is not affected by the non-compliant status of the amendment.

If applicant wishes to resubmit the after-final amendment, the ENTIRE corrected after-final amendment must be resubmitted within the time period set forth in the final Office action.